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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,592	07/08/2003	Louis Johan Wagenaar	BAY-001.01 (24877-001.01)	8286
25181	7590	03/29/2005		EXAMINER
FOLEY HOAG, LLP				AZPURU, CARLOS A
PATENT GROUP, WORLD TRADE CENTER WEST				
155 SEAPORT BLVD			ART UNIT	PAPER NUMBER
BOSTON, MA 02110				1615

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/615,592	WAGENAAR, LOUIS JOHAN
	<b>Examiner</b>	<b>Art Unit</b>
	Carlos A. Azpuru	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 December 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3,4,6-11,13-18,20-25 and 30-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,4,6-8,10,11,13-15,17,18,20-22,24,25,27,28,30,31,33 and 34 is/are rejected.
- 7) Claim(s) 3,9,16,23 and 32 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

Receipt is acknowledged of the amendment, remarks, and information disclosure statement filed 12/28/2004.

The following rejection is maintained with regard to claim 25:

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 25 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Park et al.

Park et al disclose contact lenses impregnated with solutions of Vitamin A, Vitamin E, ascorbic acid, and other antioxidants such as glutathione (see Abstract; col. 4, lines 7-42). The compounds are used to prevent proteinaceous deposits. Kits only contain the lenses and impregnating solution. The instant claim is clearly anticipated by Park et al.

***Response to Arguments***

Applicant's arguments filed 12/28/2004 have been fully considered but they are not persuasive.

Applicant argues that the claims have been amended to exclude the components taught by Park et al. This amendment has not been made to claim 25. The reference to Park et al therefore anticipates claim 25.

The following are new rejections of the claims based on the amendment made to them:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4, 11, 18, 25, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4, 11, 18, and 30 are indefinite in their Markush language fails to particularly point out the members of this group. In particular, it is indefinite as to how “and selenium, calcium and zinc” fit into this Markush Grouping. Presumably, they refer to salts of the members of the Markush Group. Clarification is requested.

Claims 1, 4, 11, 18, and 30 are also indefinite in that members of the Markush Group still appear to be coextensive. For example, "honey and bee products" would appear to overlap. The same can be said for gelatin and collagen.

Claim 25 is also indefinite in that paragraph two of the claim sets out that the suitable component is for the protection and/or care and or treatment of eye-disease. Paragraph 3 sets out that the suitable component is for "treatment or prevention of allergic symptoms, or for the treatment of eye-diseases. Clarification is requested as to what the intended function of the suitable component since both paragraphs appear to define different treatments.

It should be noted that given the state of the art, the term "prevention of allergic reactions" has been reviewed. Although applicant only cites cromoglycate as an example of these compounds the art is replete with examples of other compounds such as prostaglandins and antihistamines which the ordinary practitioner of ophthalmology would recognize as functioning in a similar way. As such, no rejection will be made under 35 USC, 112, first paragraph, for enablement.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,4, 6, 7, 8, 10, 11, 13-15, 20, 21, 22, 24, 27, 28, 30 and 33. rejected under 35 U.S.C. 103(a) as being unpatentable over Bisgard-Frantzen et al.

Bisgard-Frantzen et al disclose polypeptide conjugates with reduced allergenicity wherein a polypeptide is conjugated to a polymer (see Abstract). The disclosed conjugates may be used as contact lens and disinfection products (see col. 32, lines 39-41). Proteases are specifically claimed at claim 12. Those of ordinary skill would therefore expect similar therapeutic results from the use of the instantly claimed compounds given the Bisgard-Frantzen et al disclose the use of protease in eye care products for contact lenses. There are no unusual and/or unexpected results which would rebut *prima facie* obviousness. As such the instant claims would have been obvious given the disclosure of Bisgard-Frantzen et al.

Claims 1, 4, 6, 8, 10, 11, 13-15, 17, 18, 20-22, 24, 25, 30, 31, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leahy et al.

Leahy et al disclose the use of a mucin formulation which may be presoaked into a contact lens. The composition is used for treating eye irritation (see Abstract). The conditions treated in clued kerato-conjunctivitis sicca (col. 1 , lines 44-65), which is an allergic reaction of the eye, as well as dry eye. Since mucin is a bioactive in this case, it is considered a medicine. It may be in the form of a solution, ointment, gel or ocular insert (see claims 2-5). The reference does not specify whether the lens is a day lens, but is generic to all contact lenses. Those of ordinary skill would therefore expect similar therapeutic results from the use of the instant invention in the conjunction with a contact lens given the disclosure of Leahy et al. As such, the instant method and composition claims are obvious in view of Leahy et al.

Claims 3 , 9, 16, 23, and 32 are objected to as dependent upon a rejected base claim.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ca

CARLOS A. AZPURU  
PRIMARY EXAMINER  
GROUP 1500